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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,358	06/22/2001	Sean H. Adams	10716/66	8903

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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,358	ADAMS ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D	1636	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-34 are pending in the present application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1-9, drawn to an isolated CGI-69 nucleic acid of the presently claimed invention, a vector, and a host cell comprising the same, classified in class 536, subclass 23.5; class 435, subclasses 320.1, 455, for examples.

II. Claims 10-12, drawn to an isolated CGI-69 polypeptide of the presently claimed invention, classified in class 530, subclass 350.

III. Claims 13-16, drawn to a CGI-69 fusion protein comprising a polypeptide fused to the carboxyterminus of a polypeptide comprising an amino acid sequence having at least 80% sequence identity to the sequence of SEQ ID NO:3, classified in class 530, subclass 402.

IV. Claim 17, drawn to an antibody that specifically binds to an isolated CGI-69 of the presently claimed invention, classified in class 424, subclass 130.1.

V. Claims 18-21, drawn to a method of treating a metabolic disorder comprising modulating the activity of CGI-69, wherein said modulating the activity of CGI-69 comprises decreasing the activity of CGI-69, can not be

classified because the method steps and specific reagents used to modulate the activity of CGI-69 are not recited.

VI. Claims 18 and 22-24, drawn to a method of treating a metabolic disorder comprising modulating the activity of CGI-69, wherein said modulating the activity of CGI-69 comprises increasing the activity of CGI-69, can not be classified because the method steps and specific reagents used to modulate the activity of CGI-69 are not recited.

VII. Claims 25-28, drawn to a method for determining whether a compound up-regulates or down-regulates expression of a CGI-69 gene in a cell, comprising contacting the cell with said compound and detecting expression of the gene, classified in class 435, subclasses 6, 7.1.

VIII. Claims 29-30, drawn to a transgenic non-human animal having a disrupted CGI-69 gene, classified in class 800, subclass 13.

IX. Claim 31, drawn to a transgenic non-human animal comprising a transgene having at least 80% sequence identity to the sequence of SEQ ID NO:1 or a complement of said sequence, classified in class 800, subclass 13.

X. Claim 32, drawn to a method of screening for a mutation in CGI-69 comprising comparing nucleic acid sequence to the sequence of SEQ ID NOs 1 or 2, classified in class 435, subclass 6.

XI. Claims 33-34, drawn to a method for measuring CGI-69 agonist or antagonist activity of a compound comprising contacting a composition

comprising CGI-69 activity with the compound, and determining a change in the CGI-69 activity, classified in class 435, subclass 4.

Claim 18 links a plurality of patentably distinct methods of treating a metabolic disorder comprising: (a) modulating the activity of CGI-69 by decreasing the activity of CGI-69, and (b) modulating the activity of CGI-69 by increasing the activity of CGI-69, that lack the unity of invention because the methods do not share a substantial common core structure or element among themselves to achieve opposite desired effects (decreasing the activity of CGI-69 vs increasing the activity of CGI-69). As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Applicant is required under 35 U.S. C 121 to elect either one of the aforementioned methods for treating a metabolic disorder.

The restriction requirement between linked inventions is subject to the non-allowance of the linking claim 18. The restriction requirement between linked inventions is subject to the non-allowance of the linking claim(s), 18.

Upon the allowance of the linking claim, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double

patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

Additionally, should Applicant elect the invention of Group V or Group VI, **further group restriction is required depending on the nature or chemical structure of the reagent utilized to modulate the activity of CGI-69**.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups I, II, III, IV, VIII and IX are unrelated. The isolated nucleic acid molecule of Group I, the isolated polypeptide of Group II, the CGI-69 fusion protein of Group III, the antibody of Group IV, the CGI-69 knockout transgenic non-human animal of Group VIII and the CGI-69 transgenic non-human animal of Group IX comprise chemically unrelated structures capable of separate manufacture, use and effect. For examples, the polypeptides, the CGI-69 fusion protein and antibodies comprise unrelated amino acid sequences, and the nucleic acid molecule comprises nucleotides, distinct in chemical structure from amino acid residues. It is further noted that the CGI-69 fusion protein has novel characteristics not found in native CGI-69 protein (see instant specification, page 36, last paragraph). The knockout transgenic non-human animal of Group VIII and the transgenic non-human animal of Group IX are living entities that differ one from the other by the genomic make-up, and being generated by distinct processes.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the methods in Groups V, VI, VII, X and XI appear to constitute patentably distinct inventions for the following reasons: These methods are directed to methods that are distinct both physically and functionally, and are not required one for the other. The method of Group V is drawn to a method of treating a metabolic disorder by decreasing the activity of CGI-69; the method of Group VI is directed to a method of treating a metabolic disorder by increasing the activity of CGI-69; the method of Group VII is drawn to a screening process for determining whether a compound up-regulates or down-regulates expression of a CGI-69 gene in a cell; the method of Group X is directed to a method of screening for a mutation in CGI-69; and the method of Group XI is directed to a method for measuring CGI-69 agonist or antagonist activity of a compound by determining a change in the CGI-69 activity. Clearly, these methods have different method steps, starting materials, different desired end-results, and therefore different technical considerations for achieving the end-results.

The product of Group I is related to the methods of Groups V, VI, VII and X as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in any of the distinct claimed

processes. It is noted that the product of Group I is not required for the making or using of the process in Group XI.

The product of Group II is related to the methods of Groups VI and XI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II can be used in any of the distinct claimed processes of Groups VI and XI. It is noted that the product of Group II is not required for the making or using of the process in Groups V, VII and X.

The product of Group III is related to the methods of Groups VI and XI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group III can be used in any of the distinct claimed processes of Groups VI and XI. It is noted that the product of Group II is not required for the making or using of the process in Groups V, VII and X.

The product of Group IV is related to the methods of Groups V and VII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group IV can be used in any of the distinct claimed processes of Groups V and VII. It is noted that the product of Group II is not required for the making or using of the process in Groups VI, X and XI.

The transgenic non-human animal products of Groups VIII and IX are unrelated to the methods of Groups V, VI, VII, X and XI, and therefore they are not required for the practice of any of these methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Species Restriction:

Should Applicants elect either Group V or VI, claims 18-22 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named metabolic disorder as recited in the Markush Group of claim 21 or claim 24.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Quang Nguyen, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER